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(54) EKG BASED HEART RATE MONITOR

GERÄT ZUR UBERWACHUNG DER HERZFREQUENZ DAS SICH AUF EKGSIGNALE STÜTZT MONITEUR DU RYTHME CARDIAQUE BASE SUR LES SIGNAUX ELECTROCARDIOGRAPHIQUES

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- (56) References cited:

FR-A- 2 073 543 US-A- 4 342 318 US-A- 3 698 386 US-A- 4 420 000

US-A- 4 938 228

US-A- 5 243 993

Description

[0001] The present invention pertains to the field of pulse monitors, and, more particularly, to the field of pulse monitors that use EKG signals to detect the pulse rate.

[0002] In the prior art, two basic types of pulse rate monitors exist. The first type uses visible or infrared radiation which is projected through the skin to detect from radiation reflected from or penetrated through capillaries under the skin, pulsations of blood flow. Typically, these devices come in the form of a digital watch with a photodetector on the face of the watch or as a desktop unit or unit that clips to a belt with a clip connected to base unit, the clip for attaching to a fingertip or earlobe. Visible or infrared light passing through the skin is detected by the photodetector and gives an indication of pulsations in blood flow in capillaries. From these pulsations, the pulse rate is calculated.

[0003] Numerous examples of this type pulse monitor exist as they are commonly found on fitness equipment such as treadmills, stationary bicycles and stair climbing machines. Another example of this type system is a pulse rate monitor wrist watch made by Casio. This watch reads both blood pressure and pulse. The watch has two sensors on top of the watch. The sensor on the lower left of the face of the watch is a photosensor which is to be covered with the wearer's right index finger. The other sensor is to be covered by the right middle finger and is an electrode to pick up the EKG signals. The bottom plate of the watch body serves as the other electrode.

[0004] There are several disadvantages to the photosensor/flow pulsation detectors. First, the finger position on the photosensor must be stable. Also, the force pressing the finger or ear lobe to the photodetector must be nominal. If the force is too high, the blood flow will be cut off, and no detection of blood flow pulsations can occur. If the force is too low, then any slight motion between the body and the sensor may cause inaccurate readings. Also, the reliability of the readings depends upon the ambient illumination (unless a separate photodiode supplies light for transmission through the skin) and upon the wavelength. Further, the flow pulse in a capillary looks like a sinusoidal waveform in shape. This makes it difficult to distinguish legitimate flow pulse signals from sinusoidally shaped noise waveforms.

[0005] The second type of pulse rate monitor is the EKG type. These type pulse monitors work by picking up an EKG signal from the heart muscle itself and calculating the pulse rate from the EKG signal. One example of this type system is a pulse rate monitor wrist watch made by Casio. This watch reads both blood pressure and pulse. The watch has two sensors on top of the watch. The sensor on the lower left of the face of the watch is a photosensor which is to be covered with the wearer's right index finger and which detects fluctuations in light passing through the finger from ambient sources to determine when blood flow pulses occur. The sensor on the lower right of the face is one of two sensors for an EKG signal. The bottom surface of the watch is the other sensor for picking up the EKG signal. To use this watch to read blood pressure and pulse, the user must first use another independent instrument to measure blood pressure and pulse in an at-rest condition. These readings are then input to the watch. After inputting this data, the watch takes about 10-20 heartbeats with the user's fingers in contact with the two contacts on the face of the watch. During these 10-20 heartbeats, the watch learns the timing between the EKG signals picked up by the EKG contacts and the corresponding blood flow pulses in an at-rest condition. This timing serves as a reference for determination of blood pressure. The operative principle is determination by the watch of the timing between the EKG signal that causes the left ventricle to pump blood to the resulting pulse of blood flow detected by the photodetector in the capillaries of the wearer's fingertip.

[0006] A drawback of this design is that the timing between the EKG pulse and the blood flow pulse changes with fitness level as the aerobic effect takes over and new blood flow paths are formed in the body. As a result, the manufacturer recommends that the basic at-rest data read from an independent instrument be updated every three months. This is inconvenient unless the owner of the watch also owns independent instruments to measure blood pressure and pulse rate. Further, the watch is incapable of measuring only pulse rate without also measuring blood pressure.

[0007] EMG noise is particularly troublesome in EKG pulse monitors because its frequency is in the same range as the frequency of the sought after EKG signal. Therefore, special signal processing must be accomplished to separate EMG noise from the desired EKG signal. One type of signal processing methodology that has been tried in the prior art is autocorrelation. The EKG signal is sensed by probes which are typically mounted on the handles of exercise equipment which the user grabs while exercising. The signals sensed by these probes, which contain the EKG signal, are passed through an autocorrelator which performs a correlation calculation between a piece of the signal represented by one buffer's worth of digital samples and an adjacent portion of the signal in time represented by another set of samples. Signal indication logic monitors the output of the autocorrelator for the presence of a periodic signal and generates a synthetic candidate heart rate signal that has the same frequency as the periodic signal in the output of the autocorrelator. The difficulty with this approach is that the EMG signals during exercise are also periodic and will cause peaks in the autocorrelator output, that do not represent periodic EKG signal.

[0008] The class of products described above are generally used by health conscious people while working out. Because of the drawbacks of the approaches described above, there has arisen a need for a reliable pulse monitor that is small and can be worn on the wrist or attached to exercise equipment and requires no electrode gel or moisture or chest strap and which can accurately find the EKG signal despite low signal to noise ratio.

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[0009] US-A-4938228 discloses apparatus according to the preamble of Claim 1.

[0010] The invention is set out in Claim 1

A convenient low-cost heart rate monitor may be provided by embodiments of the present invention. In one embodiment, a digital filter structure includes a low pass filter having a notch at 60 Hz and a bandpass filter which amplifies signals in a frequency range from 10-40 Hz and has a notch at 60 Hz. This digital filter has a recursive structure and uses integer coefficients to simplify and speed up the calculations. A four bit microcontroller may implement the digital filter. The output of the digital filter is subject to enhancement signal processing to emphasize QRS complexes indicative of human heartbeats.

[0011] One embodiment of a heart rate monitor may include at least two electrical contacts for detecting the electrical signals when placed in contact with the body, an analog circuit that conditions the electrical signals, an analog-to-digital converter coupled to receive an analog output signal from the analog circuit and convert the analog signals to a plurality of digital samples, a digital filter for receiving the digital samples and suppressing noise signals that have frequencies below about 5-15 Hertz, and signals having frequencies above about 25-40 Hertz to generate filtered data, the digital filter being a recursive filter having integer coefficients, and an enhancement signal processor to receive the filtered data and highlight signals therein that have predetermined characteristics of QRS complexes in human heartbeat signals so as to generate enhanced digital data.

[0012] In accordance with a method of an embodiment for distinguishing pulses caused by heartbeats from other pulses the method may include steps of discarding pulses that arrive at times inconsistent with plausible beat-to-beat variation in heartbeat rate as representing artifacts rather than heartbeats, and discarding pulses having amplitudes varying more than a predetermined amount from previously received pulses representing heartbeats.

[0013] A further understanding of the nature and advantages of at least preferred embodiments of the invention herein may be realized by reference to the remaining portions of the specification and the attached drawings.

[0014] Fig. 1 shows a typical application in a digital wrist watch for the EKG type heart rate monitor according to the teachings of the invention.

[0015] Fig. 2 is a block diagram of the preferred embodiment of the electronics of the invention.

[0016] Fig. 3 is an illustration of some of the waveforms involved in illustrating some of the issues dealt with by the teachings of the invention.

[0017] Fig. 4 is an overview flow chart of the software architecture according to the teachings of the invention.

[0018] Fig. 5 is a graph of the filter response of a digital low pass filter used in the preferred embodiment of the invention.

[0019] Fig. 6 is a graph of the filter response of a digital bandpass filter used in the preferred embodiment of the invention.

[0020] Fig. 7 is a graph of the total filter response resulting from combining the effects of the digital low pass filter and the digital bandpass filter.

[0021] Fig. 8 is a more detailed flow diagram of the enhancement signal processing of the right branch in Fig. 4.

[0022] Fig. 9 is an illustration of the waveforms that illustrate the operation of the processing of Fig. 8.

[0023] Fig. 10 is a flowchart describing steps of post-processing to determine the user's heart rate.

[0024] Fig. 11 is a flowchart describing further steps of post-processing to determine the user's heart rate.

[0025] Referring to Fig. 1, there is shown a typical application, in a digital wrist watch for the EKG type heart rate monitor according to an embodiment. The digital watch 10 includes a display such as LCD display 12 which is used to display the time, and when the pulse monitor mode is selected, displays the user's heart rate. In some embodiments, a separate display can be used to show the pulse rate with the time simultaneously displayed in display 12. The digital watch embodiment uses a three contact approach to help eliminate noise. Two electrical contacts 14 and 16 are placed on the front of the watch for the user to place his or her fingers on when the pulse mode is entered. A third electrical contact is located on the back side of the watch and is indicated in phantom at 18. The three contacts are connected to a differential amplifier inside the watch so that common mode noise is suppressed. It should be understood that the present invention is not limited to three contacts. The circuitry and software described below is incorporated into the watch 10 so that the unit is stand alone.

[0026] Referring to Fig. 2, there is shown a block diagram of the preferred embodiment. Block 58 represents the electrical contacts of any of the embodiments discussed above. Block 60 is a differential amplifier or instrumentation amplifier that is coupled via bus 62 to the contacts. The differential amplifier amplifies the analog signals on the three conductors of bus 62. The common input on bus 62 is coupled to analog ground and the two remaining conductors are coupled to the plus and minus inputs of the differential amplifier. The differential amplifier serves to provide gain and to simultaneously eliminate common mode noise in the signal such 60/50 Hertz hum etc. The gain of the differential amplifier is set at a relatively low figure of 1-10 to prevent saturation of the operational amplifiers therein by the low frequencies that are still in the analog signal.

[0027] Next, the output of the amplifier is filtered by an active analog bandpass filter 64. Active filters using RC components in operational amplifier circuits are used to implement the bandpass filter. The passband of this filter is

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centered on some frequency between 5 and 20 Hertz, preferably 10-15 Hertz, and has a passband of approximately 5-40 Hertz. The purpose of this bandpass filter is to remove high frequencies from the analog signal to prevent aliasing. The low frequency corner of the passband also eliminates DC components and any low frequency drift of the baseline caused by respiration muscle contractions or other muscle contractions such as typically occur when the user is exercising. The gain of the bandpass filter is set between 1 and 10 at the center frequency. A passive bandpass filter could be used, but generally is not preferred since it requires too many components and the rolloff is not sharp enough. In the preferred embodiment, the passband filter is comprised of two separate hardware filters: a low pass filter with a first order rolloff and a corner frequency between 25-40 Hertz; and a high pass filter with a second order rolloff with a corner frequency of from 5-15 Hertz. The reason these two filters have different order rolloffs is to allow the differentiator to emphasize the high frequency components in the signal in a manner described below. In other words, the steeper rolloff on the low frequency corner provides better selectivity, while the less steep rolloff on the high frequency corner allows more high frequency component to reach the differentiator such that the differentiator will generate bigger slope numbers because of the sharp peaks in the signal represented by the data reaching the differentiator because of the higher content of high frequency components in the analog signals reaching the analog-to-digital converter. These sharper comers cause the differentiation operation in the digital signal processing portions of the circuit to be described below to generate higher peaks. These higher peaks are filtered out by the moving average function, but in the process, the average rises thereby causing the EKG signals to stand out better against the background noise. [0028] Next, the analog signal is amplified in amplifier 66 which has a gain of 50-1000 so that the overall gain is about 1000-10,000.

[0029] Next, the analog output of the amplifier 66 is applied to the input of an analog-to-digital converter (hereafter AD converter) 68, which, in the preferred embodiment is integrated onto the microcontroller integrated circuit. The analog signal is converted to 8-bit digital samples at a sampling rate of 180 Hertz, or some other multiple of 60 Hertz preferably. Other sampling rates can also be used so long as the high frequency components of the real signal from the electrodes have been filtered out prior to the real signal reaching the analog-to-digital converter. If these high frequency components have not been filtered out, alias signals will appear in the EKG frequency range resulting from beating of the sampling rate with the high frequency components. This is why use of an analog bandpass filter in front of the analog-to-digital converter is preferred. Different numbers of bits in each sample could be used as well as a higher or lower sampling rate, but 180 Hertz is preferred to make the digital filtering easier since the 180 Hertz sampling rate is a multiple of the 60 Hertz frequency of a common source of noise. Further, the coefficients for the digital signal processing stages described below are set for a sample rate of 180 samples per second, so if other sample rates are used, the coefficients must be optimized again. In some embodiments, the AD converter is part of a microcontroller integrated circuit 70. The AD converter should be able to operate on a 3 volt supply or some supply voltage easily achievable with batteries and, for size considerations in some embodiments, preferably has a serial format output data stream if the AD converter is not integrated onboard the microcontroller.

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[0030] The digital data stream from the AD converter is input to the microcontroller 70 for further signal processing to be described below. The microcontroller is preferably a 4-bit or 8-bit machine such as a Samsung KS57C2408 or Hitachi H8/3812 or equivalent. These microcontrollers have on-board analog-to-digital converter, dual clocks, LCD drive and buzzer drives. There is no need for an on-board DSP or a separate DSP since the digital filter coefficients are integers which substantially simplifies and speeds up processing in the software filtering modules. The microcontroller is also coupled to a number of user interface peripherals represented by block 72. The user interface peripherals include LCD displays, mode control switches, buzzer(s), sensors for monitoring track/wheel speed or as part of an automatic feedback loop which will cause more drag on the wheel/track when the heart rate drops below a target range, and output ports to which different resistors may be connected to change the gain of the operational amplifiers, output signals to implement automatic load variation in embodiments where the drag on the belt/wheel is automatically varied in accordance with the user's heart rate, such as circuitry to change the gears on a mountain bike to a lower gear or higher gear automatically based upon the user's heart rate, and alarm units to give users audible alarms when something is not working or needs adjustment. The microcontroller incorporates a main clock 74 which can be shut down in power down mode while an independent digital clock also incorporated within the microcontroller is not disabled during power down mode.

[0031] In some embodiments, a separate digital clock integrated circuit 76 with its own clock 78 serves to keep track of the time/date etc. and control the display thereof. In alternative embodiments, the digital clock chip can be any digital clock chip where display 80 displays only time and date so long as the clock chip has an interface to the microcontroller 70 to receive heart rate data. However, in the preferred embodiment, digital clock IC 76 is incorporated into the microcontroller and receives for display data encoding the heart rate reading, calories burned, speed, distance covered, exercise time etc. via the conductors of bus 82 for display on LCD display 80.

[0032] There follows a discussion of the digital signal processing implemented by the firmware which controls operations of the microcontroller 70. However, to better understand the approach used, the characteristics of a typical EKG signal and an EKG signal with noise will first be discussed. Referring to Fig. 3, there is shown a number of waveforms

on time lines (A) through (G). Time line (A) shows a typical EKG signal, which is sometimes referred to as a QRS complex. An EKG signal is comprised of a first small positive peak designated as P on time line (A), followed by a negative peak designated Q. After the negative Q peak, a very large positive peak immediately follows which is designated as R on time line (A). The R peak is immediately followed by a negative S peak which is immediately followed by a smaller positive T peak. The slope of the R peak is symmetrical on both sides and has a unique characteristic value. [0033] Time line (B) shows a EKG signal superimposed with 60 Hertz line interference. Time line (C) shows the result of passing the signal of time line (B) through a second order Butterworth lowpass filter. The signal on time line (C) still exhibits some 60 Hertz noise. Time line (E) represents and EKG signal superimposed upon a low frequency noise sources such as respiration EMG or exercise EMG signals. Time line (F) shows the result of passing the signal of time line (B) through a second order Butterworth high pass filter showing distortion of the signal from the action of the filter. Time line (D) shows the signal resulting from passing the noisy signal of time line (B) through an integer coefficient low pass filter such as is used in the invention. Time line (G) shows the signal resulting from passing the signal of time line (E) through an integer coefficient high pass filter such as is used in the invention. Both low and high pass integer coefficient filters are used in the invention to eliminate both 60 Hertz noise and low frequency noise.

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[0034] Referring to Fig. 4, there is shown a flow diagram of the main processing carried out by microcontroller 70 on the digital samples received from the AD converter 68. The digital filtering which results in the signals on time lines (D) and (G) in Fig. 3 is represented by the digital filtering block 90. The function of this block is to remove high and low frequency noise from the digital samples.

[0035] The digital filtering steps represented by block 90 comprises, in the preferred embodiment, a first step of low pass filtering the incoming digital data with a low pass filter having a notch at 60 Hertz and then passing the resulting filtered data through a bandpass filter which amplifies the signals in a frequency range from 10-40 Hertz and has a notch at 60 Hertz. The reason a low pass filtering step is used prior to passing the data through is to remove remaining undesired high frequency components in the incoming data prior to passing the signals through the bandpass filter for amplification and further filtering.

[0036] Fig. 5 represents the frequency response of the preferred embodiment for the digital low pass filter implemented by the preferred embodiment of the digital filtering step 90 in Fig. 4. This digital filtering is achieved by implementing a recursive filter having integer coefficients to simplify and speed up the calculations required to implement the filter. However, any digital or analog filter that implements a frequency response roughly equivalent to the frequency response of Fig. 5 will suffice for purposes of practicing the invention, e.g., non-recursive, recursive with different integer coefficients or floating point coefficients, separate DSP etc., analog or any combination of the above. In fact, the low pass filtering step can be eliminated altogether in some embodiments. The purpose of the low pass digital filter is to remove 60 Hertz noise and to enhance signal to noise ratio.

[0037] Fig. 6 represents the frequency response of the preferred embodiment of the bandpass filter implemented as the second stage of digital filtering represented by block 90 in the preferred embodiment. This digital filtering frequency response is achieved by implementing a recursive filter having integer coefficients to simplify and speed up the calculations required to implement the filter. However, any digital filter that implements a frequency response roughly equivalent to the frequency response of Fig. 6 will suffice for purposes of practicing the invention, e.g., non-recursive, recursive with different integer coefficients or floating point coefficients, separate DSP etc. or any combination of the above. The bandpass filter function could also be done using an analog filter. One purpose of the bandpass filter is to reduce low and high frequency EMG signals caused by exercise, respiration and muscle tremor in addition to further reducing 60 Hertz hum noise. Some of the above mentioned EMG signals lie outside the passband and are therefore attenuated. EMG and other noise signals in the passband are removed by a learning, adaptive threshold detect operation and further uses rules of reason implemented in the software to arbitrate whether pulses which exceed the adaptive threshold are true heart beats or are artifacts or noise.

[0038] The low pass filtering step can be eliminated in some alternative embodiments since the bandpass filter also removes the high frequencies. However, the low pass filter is preferred because if it is not present, there is less effective filtering out of 50 Hertz noise which is only an issue if the invention is to be used in any European or other country where 50 Hertz power is used.

[0039] Returning to the consideration of the overall digital signal processing represented by Fig. 4, after digital filtering is performed, two different processes are performed to find the EKG signal in the filtered data. In the preferred embodiment, only the enhancement signal processing represented by block 92 is performed. In another embodiment, template matching or cross-correlation is also used to provide alternative results which can be cross-checked against the results of the enhancement signal processing.

[0040] Referring to Fig. 8, there is shown a flow chart of the basic operations that are performed in the enhancement signal processing block 92. The first step is differentiation, represented by block 96. The reason this differentiation operation is performed is because the filtering process removed some of the information content of the EKG signal, but there is still a fairly high spectral content of high frequency Fourier components of the EKG signal caused by the Q, R and S peaks which is within the passband of both the analog and the digital filters. To enhance this component,

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the differentiation process is performed on the array of sample data to find the slopes of all peaks in the data. The incoming filtered data has a signal waveform which can look like the waveform at time line A in Fig. 9. The differentiation process receives this waveform and outputs a waveform that looks like the signal on time line B in Fig. 9.

[0041] The slopes of the two sides of each peak in the signal on time line A are successively positive and then negative. Because a moving average (an integration step) is to be calculated to smooth out the output of the enhancement signal processing output and to improve the signal to noise ratio, negative peaks are undesirable because they tend to cancel positive peaks and make the signal to noise ratio worse. To get rid of the negative peaks and possibly improve the signal to noise ratio, in the preferred embodiment, a squaring operation represented by block 98 is performed. The squaring operation outputs a waveform like that shown on time line C of Fig. 9. Note that all negative peaks are converted to positive peaks.

[0042] Because squaring requires multiplication, and because multiplication is slow and consumes too much computing resource, the preferred embodiment is to substitute a look up table containing the squares of all values likely to be found in the input signal to avoid the processing necessary in multiplication. This is much faster than actually performing the multiplication. In an alternative embodiment, an "absolute value" step can be performed for block 98. This absolute value operation receives both positive and negative peaks and outputs a signal which is all positive peaks, each representing the absolute value of the magnitude of a corresponding positive or negative peak. Squaring is preferred since this has the effect of multiplying the size of the peaks in the signal thereby enhancing the signal to noise ratio. More than one squaring operation may be applied, preferably two, to further enhance the signal-to-noise ratio. [0043] Finally, a moving average is computed as represented by block 100. The purpose of calculating this moving average is to smooth out any sharp spike-like peaks in the output of the squaring operation or absolute value step. The moving average computation is like an integration which calculates the area under each peak in the output from the squaring or absolute value step. The moving average step also increases the signal to noise ratio by taking each pair of peaks in the signal output by block 98 and summing the area under each curve. This enhances the amplitude of the resulting single peak which results from each pair of adjacent peaks in the signal on time line C. For example, peak 102 results in the output of the moving average step from the integration or filtering of the pair of peaks 104 and 106 that arrived from the squaring step. The moving average is calculated by taking a predetermined number of sequential samples and adding their values and then dividing the sum by the number of samples so added. The individual samples in each moving average can be weighted in some embodiments. This process is carried out continuously for each contiguous group of samples.

[0044] Equation (1) below represents the mathematical expression which completely specifies the digital signal processing which implements the recursive low pass filter step of block 90 in Fig. 4 with a notch at 60 Hertz.

Equation (1):
$$Y_n = 1/8*(2Y_{n-1} - Y_{n-2} + X_n - 2X_{n-4} + X_{n-8})$$

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The Y terms represent previous outputs such that Y_{n-1} represents the most recent previous output while Y_{n-2} represents the second most recent previous output. The X terms represent recent data, except that the result of a previous stage's calculation, e.g., Y_n in equation 1 becomes raw data point X_n for the next stage, e.g., X_n in Equation (2) below is actually the result Y_n from the calculation process represented by Equation (1). For example X_n represents the most recent data while X_{n-4} represent the fourth most recent data and so on. Note how the coefficients of the recursive filter specification represented by Equation (1) are all integers thereby greatly speeding up and simplifying the calculation. There are many different combination of coefficients which can result in acceptable filter transfer functions. There may even be other filter specifications with more points or different subscripts which result in acceptable filter responses. Equation (1) only represents one acceptable example, and any alternative that results in a similar range of frequencies in the passband as shown in Fig. 5, and relatively similar gain levels will be acceptable. The factor 1/8 in the equation of Equation (1) is a normalization factor based upon the gain of the filter.

[0045] Equation (2) represents the mathematical expression which completely specifies the digital signal processing which implements the recursive bandpass filter step of block 90 in Fig. 4 with a notch at 60 Hertz.

Equation (2):
$$Y_n = 1/12*(2Y_{n-1} - 3Y_{n-2} + 2Y_{n-3} + X_n - 2X_{n-6} + X_{n-12})$$

The same can be the about other possible alternatives to the filter specification of Equation (2) as was said about Equation (1). The factor 1/12 in the equation of Equation (2) is a normalization factor based upon the gain of the filter. [0046] Equation (3) represents the mathematical expression which completely specifies the digital signal processing which implements the differentiation step 96 in Fig. 8.

Equation (3):
$$Y_n = 1/4^*(2^* X_n + X_{n-1} - X_{n-3} - 2^* X_{n-4})$$

Many other combinations of weighting coefficients, numbers of sample points and possibly even different subscripts exist. For example, the denominator 4 in Equation (3) is chosen so as to make the result of the differentiation process larger such that the input data to the squaring process is larger. This results in greater dynamic range. However, other denominator factors exist which can be used without departing from the invention defined in the claims. Any such combination that result in a filter characteristic that has the same relative range of frequencies within the first major loop of the transfer function where most of the useful work gets done will be acceptable to practice the invention. For example, different numbers of sample points with a different divisor will also work to practice the invention.

[0047] Equation (4) represents the mathematical expression which completely specifies the digital signal processing which implements the moving average step 100 in Fig. 8.

Equation (4):

$$Y_N = \frac{1}{64} \sum_{i=0}^{7} X_{N-i}$$

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The moving average function has the effect of amplifying the low frequency components. The number of points selected for the "window" over which the moving average is calculated is important in that it defines where the first notch is in the transfer function which has the characteristic of defining how high the amplitude is of the resulting moving average peak. Eight points were selected in the preferred embodiment to enhance the signal-to-noise ratio by raising the amplitude of the peak that results from each peak pair in the signal from the squaring or absolute value operation of block 98 in Fig. 8. Other values for signal-to-noise ratio would also work, but perhaps not as well. For example, 16 points would smooth the output more, but the amplitude of the peak is lower. A number of points fewer than 8 may result in a sharper peak with more adjacent noise thereby resulting in lower signal to noise ratio. The 1/64 factor in front of the summation is a scaling factor which can be used as a digital gain control factor. In some embodiments, the adaptive learning process will be used to affect this digital gain control factor based upon characteristics found in the sample data. [0048] Referring again to Fig. 4, in an alternative embodiment, a second type of signal processing of the digital data after digital filtering is carried out as a cross check against the results of the enhancement signal processing or as an alternative thereto. The alternative or additional processing is symbolized by block 108 and involves template matching in the preferred embodiment or cross-correlation where adequate processing power is available to do the multiplications involved in the cross-correlation calculation. The template matched filtering is basically a crude but fast way of performing rudimentary cross-correlation to determine the degree of likeness between two waveforms. Template matching is discussed in greater detail in the parent application, U.S. Patent App. No. 08/554,373.

[0049] The processes of block 108 and 92 in Fig. 4 have the effect of removing artifacts and noise and enhancing the peaks in the incoming data which are likely to be actual QRS EKG waveforms. In the process of block 92, the differentiation step of block 96 in Fig. 8 tends to remove or suppress EMG peaks and enhance EKG peaks because the EKG peaks have steeper slopes and sharper tips than typical EMG waveforms. This results in larger numbers being output from the differentiator for EKG signals that have been differentiated than for EMG signals. This fact translates to higher peaks in both the positive and negative amplitudes in the signals on time line B of Fig. 9 representing the differentiator results from differentiating EKG QRS waveforms than result from differentiation of typical EMG pulses. This further suppresses EMG noise and enhances the signal to noise ratio.

[0050] The template matching or cross-correlation process of block 108 removes artifacts by virtue of suppressing peaks that do not have the shape of the template. The template is designed to simulate closely the shape of the QRS waveform in a typical EKG waveform. In some embodiments, the shape of the template will be adjusted "on-the-fly" after actual EKG signals are isolated for this particular user so as to more closely match the shape of the QRS waveform of this particular user. Suppressing of EMG waveforms and other noise and artifacts occurs because these spurious signals do not have the same shape as the template and therefore result in lower correlation peaks in the output data of the template matching process.

[0051] After enhancement of the digital data and removal of as many artifacts as possible in the enhancement process, either by the process of block 92 or block 108 in Fig. 4, the resulting digital data is analyzed to determine the user's current heart rate. This is done by post-processing heart rate determination module 109 in Fig. 4. The process represented by block 109 could be any one of a large number of different types of discrimination or arbitration routines to decide which of the pulses in the filtered, enhanced data from either path 110 or path 112 in Fig. 4 represent actual heart beats and to calculate the heart rate therefrom.

[0052] Fig. 10 is a flowchart describing steps of post-processing to determine the user's heart rate in accordance with one embodiment of the present invention. Fig. 10 shows steps of first establishing that a series of pulses correspond to the user's heartbeat. The steps of Fig. 10 rely on both the amplitudes and positions of pulses to establish that a series of pulses correspond to heartbeats rather than noise artifacts that have survived the previous processing stages. At step 1002, post-processing heart rate determination module 109 awaits the first pulse above a predetermined amplitude threshold. In one embodiment, this threshold is 1/4 of the full scale value of the A/D converter output. Once this pulse arrives, post-processing heart rate determination module 109, at step 1004, looks for a second pulse having an amplitude within 50% of the amplitude of the first pulse and arriving at a time indicative of a realistic human heart rate, e.g., between 40 and 240 bpm.

[0053] If no second pulse meeting these criteria arrives, processing returns to step 1002 to reawait a first pulse. It should be noted that if a second pulse arrives but does not meet the criteria for a second pulse, it may meet the criteria for a first pulse and step 1002 will be skipped. If a second pulse meeting these criteria arrives, this suggests that both the first and second pulse may both be heartbeats. At step 1006, post-processing heart rate determination module 109 awaits a third pulse having 50% of the amplitude of the average amplitude of the first and second pulses and arriving at a time defining an interpulse period having a duration within 6.75% of the interval between the first pulse and the second pulse.

[0054] If no such third pulse arrives, the first two pulses are discarded and processing returns to step 1002 to await a new first pulse. If a third pulse meeting the criteria arrives, post-processing heart rate determination module 109 begins a process of confirming the current measured heart rate by awaiting a fourth pulse. However, post-processing heart rate determination module 109 takes extra precautions to insure that the fourth pulse is not noise. First, at step 1008, post-processing heart rate determination module 109 waits for 50% of an average period determined to be the average of the period between the first and the second pulses and the period between the second and the third pulses. [0055] Post-processing heart rate determination module 109 then looks for a noise pulse that might begin before the expected arrival of the fourth pulse and extend into the expected arrival period. In one embodiment, the threshold for detecting such noise pulses starts at approximately 50% of the mean amplitude of the first three pulses and decreases in four steps to approximately 19% of the mean amplitude. At step 1010, post-processing heart rate determination module 109 spends the next 12.5% (or fourth of the remaining time) of the period until the expected arrival of the fourth pulse checking for a noise pulse having an amplitude above the initial noise pulse threshold of 50%. If such a pulse begins but does not end during this subperiod, then at step 1012, post-processing heart rate determination module 109 sets a noise pulse flag. If no such pulse arrives, or after step 1012, post-processing heart rate determination module 109 checks if a previous noise pulse ends during this subperiod without a new one starting, at step 1014. If a previous pulse ends, then the noise pulse flag clears at step 1016. After the noise pulse flag clears, or if the noise pulse flag is not cleared, at step 1018, the noise pulse threshold is lowered for the next subperiod of the last 50% of the period before the expected arrival of the fourth pulse. Then post-processing heart rate determination module 109 checks at step 1020 whether, the next 12.5% subperiod is the last before the expected arrival of the fourth pulse. If the next subperiod is not be the last, post-processing heart rate determination module 109 returns to step 1010 to adjust the noise pulse flag.

[0056] If the next 12.5% subperiod is the last, at step 1022, the preferred embodiment sets and clears the noise pulse flag based on any detected pulse activity. The noise pulse threshold has now stepped down to its minimum. Once the last 6.75% of the expected interpulse period arrives, a new pulse may be the expected heartbeat. If, at step 1026, a pulse arrives within 6.75% of the expected arrival time, and having amplitude within 50% of the average of the first three qualified pulses, and while the noise pulse flag is clear, then this is considered to be the fourth qualified pulse and the heart rate based on the first four qualified pulses is read out at step 1028. Requiring the noise pulse flag to be clear eliminates artifacts caused by earlier noise pulses extending into the expected arrival time of the fourth pulse. If no such fourth pulse arrives, the first three pulses are discarded and post-processing heart rate determination module 109 proceeds to step 1002 to await a new first pulse.

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[0057] After step 1028, post-processing heart rate determination module 109 may be considered to be in a steady state, with a current displayed heart rate being based on the current average period between pulses. However, post-processing heart rate determination module 109 continues to guard against erroneous readings caused by noise. The process of qualifying successive pulses as heartbeats is similar to the steps of qualifying the fourth pulse as shown in Fig. 10. In facts, steps 1102, 1104, 1106, 1108, 1110, 1112, and 1114 are essentially identical to steps 1002-1020 of Fig. 10. In Fig. 11, post-processing heart rate determination module 109 looks for noise pulses during the last 50% of the period between the last heartbeat and the expected arrival time of the next heartbeat as determined by the mean interpulse period. At step 1116, during the last 12.5% of this interpulse period, post-processing heart rate determination module 109 continues to set and clear the noise pulse flag based on received noise pulses but also awaits the next heartbeat pulse during the last 6.75% of the interpulse period. At step 1118, post-processing heart rate determination module 109 determines if a pulse arrives within 50% of the median amplitude, within 6.75% of the average period, and while the noise pulse flag is clear. If such a pulse arrives, heartbeat display continues at step 1120.

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[0058] If no such pulse arrives, then post-processing heart rate determination module 109 checks at step 1122 whether a qualified pulse has in fact arrived in the last five seconds. If no qualified pulse has arrived in the last five seconds, it is necessary to reacquire the heartbeat at step 1124 by repeating the steps of Fig. 10. If a qualified pulse has arrived in the last five seconds, heartbeat display continues at step 1120 and post-processing heart rate determination module 109 repeats the steps of Fig. 11, looking for a new qualified pulse at the next expected arrival time.

[0059] In the foregoing specification, the invention has been described with reference to specific exemplary embodiments thereof. It will, however, be evident that various modifications and changes may be made.

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1. Apparatus for determining heart rate from electrical signals generated within a body, comprising:

at least two electrical contacts (58) for detecting said electrical signals when placed in contact with said body an analog circuit (60), (64), (66) that conditions said electrical signals; an analog-to-digital converter (68) coupled to receive an analog output signal from said analog circuit and convert said analog signals to a plurality of digital samples; a digital filter for receiving said digital samples and suppressing unwanted signals (70); an enhancement signal (92) processor to receive said filtered data and highlight signals therein that have

an enhancement signal (92) processor to receive said filtered data and highlight signals therein that have predetermined characteristics or QRS complexes in human heartbeat signals so as to generate enhanced digital data,

characterised in that said enhancement signal processor comprises:

a differentiator (96) for determining the slope of peaks in said filtered data and generating a slope signal which defines the magnitude and sign of the slopes of each portion of each said peak; a squaring processor (98) for squaring the results from said differentiator; and a moving average processor (100) for computing a moving average of said positive values only signal and outputting a moving average signal which defines said moving average over time.

2. The apparatus of claim 1 wherein said analog circuit comprises:

a differential amplifier (60) having a gain of from approximately 1-10 coupled to said electrical contact means for amplifying any signals detected by said electrical contact means and suppressing any common mode noise; and

an analog bandpass filter (64) coupled to receive the output of said differential amplifier and having a passband from approximately 5 to 40 Hertz, said bandpass filter comprising a low pass analog active filter having a first order rolloff characteristic with a corner frequency between 25 and 40 Hertz, and a high pass analog active filter having a second order rolloff characteristic with a corner frequency between 5 and 15 Hertz.

- 3. The apparatus of claim 1 or claim 2 wherein said analog-to-digital converter (68) uses a sample rate that is a multiple of the powerline AC voltage frequency;
- 4. The apparatus of any preceding claim wherein said digital filter (90) receives said digital samples and suppressing noise signals that have frequencies below 5-15 Hertz and signals having frequencies above about 25-40 Hertz to generate filtered data, said digital filter being a recursive filter having integer co-efficients.
 - 5. The apparatus of any preceding claim wherein said differentiator is a digital signal processor which computes the mathematical expression

$$Y_n = [2X_n + X_{n-1} - X_{n-3} - 2X_{n-4}]/4,$$

where

Y_n = represents slope at any particular sample time N,

 $2X_n$ = represents twice the amplitude of the most recent digital data sample from the output of the previous filter, X_{n-1} = represents the amplitude of the next most recent digital data sample from the output of the previous filter,

 X_{n-3} = represents the amplitude of the third most recent digital data sample in the stream from the output of the previous filter, and

 $2X_{n-4}$ = represents twice the amplitude of the fourth most recent digital data sample from the output of the previous filter.

- 6. The apparatus of any preceding claim wherein said moving average processor calculates said moving average as a stream of digital data samples with the most recent digital data sample representing the moving average represented by Y_N and wherein each Y_N in said moving average data stream is calculated by summing the 8 most recent data samples in said stream of data samples representing said filtered data and dividing the sum by 64.
- 7. Apparatus according to any preceding claim, further comprising a post processing heart rate determination signal processor arranged to analyze said digital data to determine the heart rate therefrom.
- 8. The apparatus of Claim 7 further comprising a display for displaying said heart rate determined by the post-processing heart rate determination signal processor means (109).
 - 9. Apparatus according to any of Claims 1 to 6, further comprising post-processing heartbeat determining means configured to distinguish heartbeat pulses from other pulses by virtue of being configured to:
- discard pulses that arrive at times inconsistent with plausible beat-to beat variation in heartbeat rate as representing artifacts rather than heartbeats; and discard pulses having amplitudes varying more than a predetermined amount from previously received pulses representing heartbeats.
- 25 10. Apparatus according to Claim 9 further configured to:

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identify an artifact pulse arriving before an expected arrival time of a heartbeat pulse; and identify a pulse that arrives at said expected arrival time as a heartbeat pulse only if said artifact pulse has subsided.

- 11. Apparatus according to Claim 9 or 10 configured to discard pulses that arrive at a time indicative of a change of period between heartbeats greater than approximately 6.75%.
- 12. Apparatus according to Claim 9, 10 or 11 configured to discard pulses that have amplitudes varying more than 50% from previously received pulses representing heartbeats.
 - 13. Apparatus according to Claim 10 configured to:

after approximately 50% of a period between a last heartbeat pulse and said expected arrival time of a heartbeat pulse, set a noise pulse threshold for detecting artifact pulses; lower said noise pulse threshold until said expected arrival time; and identify non-heartbeat pulses above said noise pulse threshold as artifact pulses.

14. A method of detecting a heartbeat rate among unwanted signals, comprising the steps of:

sensing signals from a body using electrodes in contact with the skin of the body; amplifying the signals;

filtering out noise below and above the frequency range in which the desired heartbeat rate will lie so as to provide a filtered analog signal;

converting the filtered analog signal to a plurality of digital samples;

digitally filtering the digital samples to remove unwanted signals so as to generate filtered digital samples; digitally processing the filtered digital samples to enhance heartbeat peaks represented therein to provide enhanced digital samples, characterised by

differentiating the filtered digital samples to determine the slope of peaks encoded therein to provide differentiation digital samples,

squaring the amplitude of signals encoded in said differentiator digital sample to provide squared digital samples, and

computing a moving average of said squared digital samples; and processing said enhanced digital samples

to determine said heartbeat rate.

15. The method of Claim 14 wherein the step of digitally filtering the digital samples comprises the step of recursively filtering the sample data derived from the signals sensed from said body according to the following recursive filter specifications, recursively low pass filtering according to the equation:

$$Y_n = 1/8 (2Y_{n-1} - Y_{n-2} + X_n - 2X_{n-4} + X_{n-8})$$

where,

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Yn represents the output digital sample on each iteration,

 Y_{n-1} and Y_{n-2} represent previous outputs such that Y_{n-1} represents the most recent previous output while Y_{n-2} represents the second most recent previous output,

and wherein

X terms such as X_n , X_{n-4} and X_{n-8} represent recent raw data inputs such that X_n represents the most recent raw data input, X_{n-8} represents the 4th most recent raw data input, and data input, and

recursively bandpass filtering according to the equation:

$$Y_n = 1/12 (2Y_{n-1} - 3Y_{n-2} + 2Y_{n-3} + X_n - 2X_{n-6} + X_{n-12})$$

where,

 \dot{Y}_n represents the output digital sample of the bandpass filtering step on each iteration, and Y_{n-1} and Y_{n-2} represent previous output digital samples of the bandpass filtering step such that Y_{n-1} represents the most recent previous output while Y_{n-2} represents the second most recent previous output, and Y_{n-3} represents the third most recent previous output,

and wherein

X terms such as $X_{n_1} X_{n-4}$ and X_{n-8} represent recent sample inputs such as samples derived from the raw or analog filtered data or digital sample results of a previous stage's calculation such as the digital low pass filtering step.

- 16. The method of Claim 14 wherein said step of digital filtering removes further remnants of frequencies above and below the range of frequencies in which said heart beat will lie and to suppress powerline hum at approximately 50-60 Hertz.
- 17. The method of Claim 16 wherein said step of computing said moving average comprises the steps of:

using a computer to calculate a moving average of said squared digital samples according to the mathematical expression,

$$Y_N = \frac{1}{64} \sum_{i=0}^{7} X_{N-i}$$

where

 Y_N represents moving average at any particular, sample time N, X_{N-1} represents the amplitude of the digital data sample at time N-i.

18. The method of Claim 14 wherein said squaring of the amplitude is performed by looking up squares in a lookup table.

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- 19. A method according to any of Claims 13 to 18, further comprising distinguishing pulses caused by heartbeats from other pulses by the steps of:
 - (a) discarding pulses that arrive at times inconsistent with plausible beat-to beat variation heartbeat rate as representing artifacts rather than heartbeats; and
 - (b) discarding pulses having amplitudes varying more than a predetermined amount from previously received pulses representing heartbeats.
- 20. The method of Claim 19 further comprising the steps of:
 - (c) identifying an artifact pulse arriving before an expected arrival time of a heartbeat pulse; and
 - (d) identifying a pulse that arrives at said expected arrival time as a heartbeat pulse only if said artifact pulse has subsided.
- 15 21. The method of Claim 19 or 20 wherein step (a) comprises discarding pulses that arrive at a time indicative of a change of period between heartbeats greater than approximately 6.75%.
 - 22. The method of Claim 19, 20 or 21 wherein step (b) comprises discarding pulses that have amplitudes varying more than 50% from previously received pulses representing heartbeats.
 - 23. The method of Claim 20 wherein step (c) comprises the steps of:

after approximately 50% of a period between a last heartbeat pulse and said expected arrival time of a heartbeat pulse, setting a noise pulse threshold for detecting artifact pulses; lowering said noise pulse threshold until said expected arrival time; and identifying non-heartbeat pulses above said noise pulse threshold as artifact pulses.

Patentansprüche

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- Vorrichtung zur Bestimmung der Herzrate aus innerhalb eines K\u00f6rpers erzeugten elektrischen Signalen, umfassend:
- wenigstens zwei elektrische Kontakte (58) zur Messung der elektrischen Signale, wenn sie mit dem Körper in Kontakt gebracht werden; einen Analogschaltkreis (60), (64), (66), der die elektrischen Signale aufbereitet; einen Analog/Digital-Wandler (68), der derart gekoppelt ist, dass er ein analoges Ausgangssignal von dem Analogschaltkreis empfängt und die analogen Signale in eine Vielzahl von Digitalabtastungen umwandelt; einen digitalen Filter zum Empfang der Digitalabtastungen und zur Unterdrückung unerwünschter Signale (70); einen Aufbereitungs- bzw. Anreicherungssignalprozessor (92) zum Empfang der gefilterten Daten und zum Hervorheben von Signalen in diesem, welche vorbestimmte Eigenschaften oder QRS-Komplexe in Signalen des menschlichen Herzschlags haben, um angereicherte digitale Daten zu erzeugen;
 - dadurch gekennzelchnet, dass der Aufbereitungs- bzw. Anreicherungssignalprozessor aufweist:
 - ein Differenzierglied (96) zur Bestimmung der Steilheit von Spitzen in den gefilterten Daten und zur Erzeugung eines Steilheitssignals, das die Größe und das Vorzeichen der Steilheit eines jeden Bereichs von jeder Spitze definiert;
 - einen Quadratprozessor (98) zur Quadrierung der Ergebnisse aus dem Differenzierglied; und einen Prozessor für einen beweglichen Durchschnitt (100) zur Berechnung eines beweglichen Durchschnitts nur der Signale mit positivem Wert und zum Ausgeben eines Signals des beweglichen Durchschnitts, das den beweglichen Durchschnitt über die Zeit definiert.
 - 2. Vorrichtung nach Anspruch 1, wobei der Analogschaltkreis aufweist:

einen Differentialverstärker (60) mit einer Verstärkung von ungefähr 1 - 10 gekoppelt an die elektrischen Kontakteinheiten zum Verstärken beliebiger Signale, die von den elektrischen Kontakteinheiten gemessen werden, und zum Unterdrücken jeglicher allgemeiner Rauschmoden; und

einen Analogbandpassfilter (64), der zum Empfang des Ausgangssignals des Differentialverstärkers angekoppelt ist und ein Durchgangsband von annähernd 5 bis 40 Hz aufweist,

wobei der Bandpassfilter einen Tiefpass-Analog-Aktivfilter mit einer Abfall-Charakteristik erster Ordnung mit einer Eckfrequenz zwischen 25 und 40 Hz und einen Hochpass-Analog-Aktivfilter mit einer Abfall-Charakteristik zweiter Ordnung mit einer Eckfrequenz zwischen 5 und 15 Hz aufweist.

- 3. Vorrichtung nach Anspruch 1 oder 2, wobei der Analog/Digital-Wandler (68) eine Abtastrate verwendet, die ein Vielfaches der AC-Netzspannungsfrequenz ist.
- 4. Vorrichtung nach irgendeinem der vorhergehenden Ansprüche, wobei der Digitalfilter (90) die Digitalabtastungen empfängt und Rauschsignale unterdrückt, die Frequenzen unter 5 15 Hz haben, und Signale mit Frequenzen über circa 25 40 Hz unterdrückt, um gefilterte Daten zu erzeugen, wobei der Digitalfilter ein rekursiver Filter mit ganzzahligen Koeffizienten ist.
- 5. Vorrichtung nach irgendeinem der vorhergehenden Ansprüche, wobei das Differenzierglied ein digitaler Signalprozessor ist, der den mathematischen Ausdruck berechnet:

$$Y_n = [2X_n + X_{n-1} - X_{n-3} - 2X_{n-4}]/4,$$

wobei

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Y_n = die Steilheit zu einer beliebigen bestimmten Abtastzeit N darstellt,

 $2\ddot{X}_n$ = das Doppelte der Amplitude der jüngsten Digitaldatenabtastung aus dem Ausgangssignal des vorhergehenden Filter darstellt,

 X_{n-1} = die Amplitude der folgenden am nächsten gelegenen Digitaldatenabtastung aus dem Ausgangssignal des vorhergehenden Filter darstellt,

X_{n-3} = die Amplitude der am drittnächsten gelegenen Digitaldatenabtastung in dem Strom von Ausgangssignalen des vorhergehenden Filter darstellt, und

2X_{n-4} = das Doppelte der Amplitude der am viertnächsten gelegenen Digitaldatenabtastung aus dem Ausgangssignal des vorhergehenden Filter darstellt.

- 6. Vorrichtung nach irgendeinem der vorhergehenden Ansprüche, wobei der Prozessor für den beweglichen Durchschnitt den beweglichen Durchschnitt berechnet als einen Strom von Digitaldatenabtastungen bei dem die am nächsten gelegenen Digitaldatenabtastung den durch Y_n dargestellten beweglichen Durchschnitt darstellt und, wobei jeder Y_n in dem Datenstrom des beweglichen Durchmessers berechnet wird durch Summation der 8 am nächsten gelegenen Datenproben in dem Strom von Datenproben, der die gefilterten Daten darstellt, und durch Division der Summe durch 64.
 - 7. Vorrichtung nach irgendeinem der vorhergehenden Ansprüche, die weiter aufweist einen Signalprozessor zur Bestimmung der Herzrate nach der Verarbeitung, der zur Analyse der Digitaldaten vorgesehen ist, um daraus die Herzrate zu bestimmen.
- Vorrichtung nach Anspruch 7, die weiter aufweist eine Anzeige zum Anzeigen der Herzrate, die durch die Signalprozessoreinheit zur Bestimmung der Herzrate nach der Verarbeitung (109) bestimmt ist wird.
 - Vorrichtung nach irgendeinem der Ansprüche 1 bis 6, die weiter eine Bestimmungseinheit für den Herzschlag nach der Verarbeitung aufweist, die zur Unterscheidung von Herzschlagimpulsen von anderen Impulsen in einer Weise konfiguriert ist, um;

Impulse auszusortieren, die zu Zeiten auftreten, die unvereinbar mit einer plausiblen Schlag-zu-Schlag Variation der Herzschlagrate ist, und welche eher Artefakte als Herzschläge darstellen; und Impulse mit Amplituden auszusortieren, die um mehr als einen vorbestimmten Umfang von vorher empfangenen Impulsen variieren, welche Herzschläge darstellen.

10. Vorrichtung nach Anspruch 9, der weiter ausgelegt lst:

zur Identifizierung eines Artefaktimpulses, der vor einer erwarteten Ankunftszeit eines Herzschlagimpulses ankommt; und

zur Identifizierung eines Impulses, der zu der erwarteten Ankunftszeit als ein Herzschlagimpuls ankommt, nur falls der Artefaktimpuls abgeklungen ist.

- 11. Vorrichtung nach Anspruch 9 oder 10, die zum Aussortieren von Impulsen ausgelegt ist, die zu einer Zeit ankommen, die eine Änderung der Periode zwischen Herzschlägen anzeigt, die größer ist als ungefähr 6,75 %.
- 12. Vorrichtung nach Anspruch 9, 10 oder 11, die zum Aussortieren von Impulsen ausgelegt ist, die Amplituden haben, die um mehr als 50% von vorher empfangenen Impulsen variieren, welche Herzschläge darstellen.
 - 13. Vorrichtung nach Anspruch 10, die ausgelegt ist, um:

nach ungefähr 50% einer Periode zwischen einem letzten Herzschlagimpuls und der erwarteten Ankunftszeit eines Herzschlagimpulses einen Rauschimpulsschwellenwert zur Messung von Artefaktimpulsen zu setzen; den Rauschimpulsschwellenwert zu senken bis zu der erwarteten Ankunftszeit; und Nicht-Herzschlagimpulse oberhalb des Rauschimpulsschwellenwerts als Artefaktimpulse zu erkennen.

14. Verfahren zum Messen einer Herzschlagrate unter unerwünschten Signalen, das die Schritte aufweist:

Aufnehmen von Signalen von einem Körper durch Verwendung von Elektroden, die mit der Haut des Körpers in Kontakt sind;

Verstärken der Signale;

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Herausfiltern von Rauschen unterhalb und oberhalb dem Frequenzbereich, in dem die gewünschte Herzschlagrate liegen wird, um ein gefiltertes Analogsignal vorzusehen;

Umwandeln des gefilterten Analogsignals in eine Vielzahl von Digitalabtastungen;

digitales Filtern der Digitalabtastungen zum Entfernen unerwünschter Signale, um gefilterte Digitalsignale zu erzeugen;

digitales Verarbeiten der gefilterten Digitalabtastungen zur Aufbereitung bzw. Anreicherung darin enthaltener Herzschlagspitzen, um angereicherte bzw. aufbereitete Digitalabtastungen vorzusehen, gekennzeichnet durch

Differenzierung der gefilterten Digitalabtastungen oben zur Bestimmung der Steilheit der darin codierten Spitzen, um Differenzierglied-Digitalabtastungen vorzusehen:

Quadratbildung der Amplitude der in der Differenzierglied-Digitalabtastung codierten Signale, um quadrierte Digitalabtastungen vorzusehen; und

Berechnung eines beweglichen Durchschnitts aus den quadrierten Digitalabtastungen; und Verarbeitung der angereicherten Digitalabtastungen, um die Herzschlagrate zu bestimmen.

15. Verfahren nach Anspruch 14, wobei der Schritt des digitalen Filterns der Digitalabtastungen den Schritt aufweist, die Probendaten rekursiv zu filtern, die aus den von dem Körper aufgenommenen Signalen abgeleitet sind, entsprechend der folgenden rekursiven Filterbeschreibung.

rekursives Tiefpassfiltern nach der Gleichung:

$$Y_n = 1/8 (2Y_{n-1} - Y_{n-2} + X_n - 2X_{n-4} + X_{n-8})$$

wobei

Y_n die Ausgangs-Digitalabtastung jeder Iteration darstellt,

 Y_{n-1} und Y_{n-2} vorhergehende Ausgangsignale derart darstellt, dass Y_{n-1} das jüngste vorhergehende Ausgangssignal darstellt, während Y_{n-2} das am zweitnächsten gelegene vorhergehende Ausgangssignal darstellt,

und wobel

X Terme wie z. B. X_n, X_{n-4}, X_{n-8} die vorhergehenden Rohdateneingänge derart darstellen, dass X_n den jüngsten vorhergehenden Rohdateneingang darstellt, X_{n-4} den am viertnächsten gelegenen vorhergehenden Rohdateneingang darstellt und X_{n-8} den am achtnächsten gelegenen vorhergehenden Rohdateneingang darstellt, und rekursives Bandpassfiltern nach der Gleichung:

$$Y_n = 1/12 (2Y_{n-1} - 3Y_{n-2} + 2Y_{n-3} + X_n - 2X_{n-6} + X_{n-12})$$

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 Y_n die Ausgangs-Digitalabtastung des Bandpassfilterungsschrittes bei jeder Iteration darstellt, und Y_{n-1} und Y_{n-2} vorhergehende Ausgangs-Digitalabtastungen des Bandpassfilterungsschrittes derart darstellt, dass Y_{n-1} das jüngste vorhergehende Ausgangssignal darstellt, während Y_{n-2} das am zweitnächsten gelegenen vorhergehende Ausgarigssignal darstellt, und Y_{n-3} das am drittnächsten gelegenen vorhergehende Ausgangssignal darstellt,

und wobei

X Terme wie z. B. X_n , X_{n-4} , X_{n-8} die vorhergehenden Probeneingänge darstellen, wie etwa Proben abgeleitet aus Roh- oder Analogfilterdaten oder Digitalabtastungsergebnissen einer vorhergehenden Zustandsberechnung, wie dem digitalen Tiefpassfilterungsschritt.

- 16. Verfahren nach Anspruch 14, wobei der Schritt der digitalen Filterung weitere Fragmente von Frequenzen überoder unterhalb des Frequenzbereichs entfernt, in dem der Herzschlag liegt, und ein Netzgeräusch unterdrückt bei circa 50 -60 Hz.
- 17. Verfahren nach Anspruch 16, wobei der Schritt der Berechnung des beweglichen Durchschnitts die Schritte aufweist:

Einsatz eines Computers zur Berechnung eines beweglichen Durchschnitts der quadrierten Digitalabtastungen gemäß dem mathematischen Ausdruck,

$$Y_N = \frac{1}{64} \sum_{i=0}^{7} X_{N-i}$$

wobei,

 Y_n den beweglichen Durchschnitt zu einer beliebigen bestimmten Abtastzeit N darstellt, X_{N-1} die Amplitude der Digitaldatenabtastung zur Zeit N - i darstellt.

- **18.** Verfahren nach Anspruch 14, wobei die Quadratbildung der Amplitude durch Nachschlagen von Quadratbildungen in Nachschlagetabellen durchgeführt wird.
- 19. Verfahren nach irgendeinem der Ansprüche 13 bis 18, das zudem das Unterscheiden von Impulse aufweist, die durch Herzschläge von anderen Impulse verursacht sind, durch die Schritte:
 - (a) Aussortieren von Impulsen, die zu Zeiten auftreten, die unvereinbar sind mit einer plausiblen Schlag-zu-Schlag Variation der Herzschlagrate, sondern welche eher Artefakte als Herzschläge darstellen; und
 - (b) Aussortieren von Impulsen mit Amplituden, die um mehr als einen vorbestimmten Umfang von vorher empfangenen Impulsen, welche Herzschläge darstellen, variieren.
- 20. Verfahren nach Anspruch 19, das zudem die Schritte aufweist:
 - (c) Identifizierung eines Artefaktimpulses, der vor einer erwarteten Ankunftszeit eines Herzschlagimpulses ankommt; und
 - (d) Identifizierung eines Impulses, der zu der erwarteten Ankunftszeit als ein Herzschlagimpuls ankommt, nur falls der Artefaktimpuls abgeklungen ist.
- 21. Verfahren nach Anspruch 19 oder 20, wobei Schritt (a) das Aussortieren von Impulsen aufweist, die zu einer Zeit ankommen, die eine Änderung der Periode zwischen Herzschlägen anzeigt, die größer ist als ungefähr 6,75%.

- 22. Verfahren nach Anspruch 19, 20 oder 21, wobei Schritt (b) das Aussortieren von Impulsen aufweist, die Amplituden haben, die um mehr als 50% von vorher empfangenen Impulsen, welche Herzschläge darstellen, variieren.
- 23. Verfahren nach Anspruch 20, wobei Schritt (c) die Schritte aufweist:

nach ungefähr 50% einer Periode zwischen einem letzten Herzschlagimpuls und der erwarteten Ankunftszeit eines Herzschlagimpulses wird ein Rauschimpulsschweilenwert zum Messen eines Artefaktimpulses gesetzt; Senken des Rauschimpulsschweilenwert bis zu der erwarteten Ankunftszeit; und

Identifizierung von Nicht-Herzschlagimpulsen oberhalb des Rauschimpulsschwellenwerts als Artefaktimpulse.

Revendications

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 Dispositif pour déterminer le rythme cardiaque à partir de signaux électriques produits à l'intérieur d'un corps comprenant:

au moins deux contacts électriques (58) pour détecter lesdits signaux électriques, lorsqu'ils sont placés en contact avec ledit corps,

un circuit analogique (60), (64), (66) qui conditionne lesdits signaux électriques:

un convertisseur analogique/numérique (68) couplé de manière à recevoir un signal de sortie analogique provenant dudit circuit analogique et convertir lesdits signaux analogiques en une pluralité d'échantillons numériques; et

un filtre numérique pour recevoir lesdits échantillons numériques et supprimer des signaux indésirables (70); un processeur de signaux d'intensification (92) pour recevoir lesdites données filtrées et mettre en relief, dans ces données, des signaux qui ont des caractéristiques prédéterminées ou des complexes QRS prédéterminés dans des signaux de battements cardiaques humains de manière à produire des données numériques amplifiées,

caractérisé en ce que ledit processeur de signaux d'intensification comprend:

un circuit différenciateur (96) pour déterminer la pente de pics dans lesdites données filtrées et produire un signal de pente qui définit l'amplitude et le signe des pentes de chaque partie de chacun desdits pics; un processeur d'élévation au carré (98) pour élever au carré des résultats fournis par ledit circuit différenciateur; et

un processeur (100) de formation de moyenne mobile pour calculer une moyenne mobile desdites valeurs positives uniquement du signal et délivrer un signal de moyenne module qui définit ladite moyenne mobile dans le temps.

2. Dispositif selon la revendication 1, dans lequel ledit circuit analogique comprend:

un amplificateur différentiel (60) possédant un gain compris entre environ 1 et 10 et couplé auxdits moyens de contact électrique pour amplifier tous les signaux détectés par lesdits moyens de contact électrique et supprimer tout bruit en mode commun, et

un filtre passe-bande analogique (64) couplé de manière à recevoir le signal de sortie dudit amplificateur différentiel et possédant une bande passante comprise entre environ 5 et 40 hertz, ledit filtre passe-bande comprenant un filtre passe-bas analogique actif possédant une caractéristique de coupure du premier ordre avec une fréquence limite entre 25 et 40 hertz, et un filtre passe-haut analogique actif possédant une seconde caractéristique de coupure avec une fréquence limite comprise entre 5 et 15 hertz.

- Dispositif selon la revendication 1 ou la revendication 2, dans lequel ledit convertisseur analogique/numérique (68) utilise une fréquence d'échantillonnage qui est un multiple de la fréquence de la tension alternative de la ligne d'alimentation.
- 4. Dispositif selon l'une quelconque des revendications précédentes, dans lequel ledit filtre numérique (90) reçoit lesdits échantillons numériques et supprime des signaux de bruit ayant des fréquences inférieures à 5-15 hertz et des signaux possédant des fréquences supérieures à environ 25-40 hertz pour produire des données filtrées, ledit filtre numérique étant un filtre récursif possédant des coefficients formés de nombres entiers.

 Dispositif selon l'une quelconque des revendications précédentes, dans lequel ledit circuit différenciateur est un processeur de signaux numériques qui calcule l'expression mathématique

$$Y_n = [2X_n + X_{n-1} - X_{n-3} - 2X_{n-4}]/4$$

dans laquelle

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Y_n = représente la pente à n'importe quel instant particulier d'échantillonnage N,

2X_n = représente le double de l'amplitude de l'échantillon de données numériques le plus récent fourni par la sortie du filtre précédent,

X_{n-1} = représente l'amplitude de l'échantillon de données numériques le plus récent en second, fourni par la sortie du filtre précédent,

X_{n-3} = représente l'amplitude du troisième échantillon de données numériques le plus récent dans le flux délivré par la sortie du filtre précédent, et

 $2X_{n-4}$ = représente le double de l'amplitude du quatrième échantillon de données numériques le plus récent délivré par la sortie du filtre précédent.

- 6. Dispositif selon l'une quelconque des revendications précédentes, dans lequel ledit processeur de formation de la moyenne mobile calcule ladite moyenne mobile sous la forme d'un flux d'échantillons de données numériques, l'échantillon de données numériques le plus récent représentant la moyenne mobile représentée par Y_N, et dans lequel chaque Y_N dans ledit flux de données de la moyenne numérique est calculé par sommation des 8 échantillons de données les plus récents dans ledit flux d'échantillons de données représentant les dites données filtrées et division de la somme par 64.
 - 7. Dispositif selon l'une quelconque des revendications précédentes, comprenant en outre un processus de signaux de détermination du rythme cardiaque après traitement, agencé pour analyser lesdites données numériques pour déterminer, à partir de là, le rythme cardiaque.
- 8. Dispositif selon la revendication 7, comprenant en outre un dispositif d'affichage pour afficher ledit rythme cardiaque déterminé par les moyens (109) formant processeur de signaux de détermination du rythme cardiaque après traitement.
 - 9. Dispositif selon l'une quelconque des revendications 1 à 6, comprenant en outre des moyens de détermination du rythme cardiaque après traitement configurés de manière à établir une distinction entre des impulsions de battements cardiaques vis-à-vis d'autres impulsions, par le fait que ces moyens sont agencés pour:

éliminer des impulsions qui arrivent à des instants incompatibles avec une variation plausible d'un battement au suivant dans le rythme cardiaque, et ce comme représentant des artéfacts plutôt que des battements cardiaques; et

éliminer des impulsions ayant des amplitudes variant de plus d'une valeur prédéterminée par rapport à des impulsions reçues précédemment et représentant des battements cardiaques.

10. Dispositif selon la revendication 9, configuré en outre de manière à:

identifier une impulsion d'artéfact arrivant avant un instant d'arrivée attendu d'une impulsion de battement cardiaque; et

identifier une impulsion qui arrive audit instant d'arrivée attendu en tant qu'impulsion de battement cardiaque uniquement si ladite impulsion d'artéfact a disparu.

- 11. Dispositif selon la revendication 9 ou 10, agencé de manière à éliminer les impulsions qui arrivent à un instant indicatif d'un changement de période entre des battements cardiaques, supérieur à environ 6,75 %.
- 12. Dispositif selon la revendication 9, 10 ou 11, agencé de manière à éliminer des impulsions qui ont des amplitudes variant de plus de 50 % par rapport à des impulsions reçues antérieurement et représentant des battements cardiaques.
 - 13. Dispositif selon la revendication 10, agencé de manière à:

au bout d'environ 50 % d'une période entre une dernière impulsion de battement cardiaque et ledit instant d'arrivée attendu d'une impulsion de battement cardiaque, régler un seuil d'impulsion de bruit pour détecter des impulsions d'artéfact;

réduire ledit seuil d'impulsion de bruit jusqu'audit instant d'arrivée attendu; et

- identifier des impulsions qui ne sont pas des battements cardiaques, au-dessus dudit seuil d'impulsion de bruit, en tant qu'impulsions d'artéfact.
- 14. Procédé pour détecter un rythme cardiaque parmi des signaux indésirables, comprenant les étapes consistant à:
- détecter des signaux délivrés par un corps en utilisant des électrodes placées en contact avec la peau du corps; amplifier les signaux;

éliminer par filtrage un bruit situé au-dessous et au-dessus de la gamme des fréquences, dans laquelle le rythme cardiaque se situe, de manière à fournir un signal analogique filtré;

convertir le signal analogique filtré en une pluralité d'échantillons numériques;

filtrer numériquement les échantillons numériques pour éliminer des signaux indésirables afin de produire des signaux numériques filtrés;

traiter numériquement les échantillons numériques filtrés pour intensifier des pics de battements cardiaques représentés dans ces échantillons de manière à fournir des échantillons numériques amplifiés,

caractérisé en ce

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qu'on différentie les échantillons numériques filtrés pour déterminer la pente de pics codés dans ces échantillons pour fournir des échantillons numériques du circuit différenciateur,

qu'on élève au carré l'amplitude de signaux codés dans ledit échantillon numérique du circuit différenciateur pour produire des échantillons numériques élevés au carré, et

qu'on calcule une moyenne mobile desdits échantillons numériques élevés au carré, et qu'on traite lesdits échantillons numériques amplifiés pour déterminer le rythme cardiaque.

15. Procédé selon la revendication 14, selon lequel l'étape de filtrage numérique des échantillons numériques comprend l'étape de filtrage récursif des données échantillons dérivées des signaux détectés à partir dudit corps conformément aux spécifications suivantes de filtre récursif, avec filtrage passe-bas récursif conformément à l'équation:

$$Y_n = 1/8 (2Y_{n-1} - Y_{n-2} + X_n - 2X_{n-4} + X_{n-8})$$

dans laquelle

Yn représente l'échantillon numérique de sortie lors de chaque itération,

Y_{n-1} et Y_{n-2} représentent différents signaux de sortie, par exemple que Y_{n-1} représente le signal de sortie précédent le plus récent, tandis que Y_{n-2} représente le signal de sortie précédent le plus récent en second,

et selon lequel

les termes X tels que X_n , X_{n-4} et X_{n-8} représentent des entrées de données brutes récentes, par exemple X_n représente l'entrée de données brutes la plus récente, X_{n-4} représente l'entrée de données brutes la plus récente en 4-ème position et X_{n-8} représente l'entrée de données brutes la plus récente en 8-ème position, et et filtrage passe-bande récursif conformément à l'équation:

$$Y_n = 1/12(2Y_{n-1} - 3Y_{n-2} + 2Y_{n-3} + X_n - 2X_{n-6} + X_{n-12})$$

dans laquelle

Y_n représente l'échantillon numérique de sortie fourni par l'étage de filtrage passe-bande lors de chaque itération, et

 Y_{n-1} et Y_{n-2} représentent des échantillons numériques de sortie précédents de l'étape de filtrage passe-bande de telle sorte que Y_{n-1} représente le signal de sortie précédent le plus récent, tandis que Y_{n-2} représente le signal de sortie précédent le plus récent en second, et Y_{n-3} représente le signal de sortie précédent le plus

récent en troisième position,

et selon lequel

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les termes X tels que X_n, X_{n-4} et X_{n-8} représentent des entrées d'échantillons récentes tels que des échantillons tirés des données filtrées brutes ou analogiques ou des résultats d'échantillons numériques du calcul d'un étage précédent, tel que l'étape de filtrage passe-bas numérique.

- 16. Procédé selon la revendication 14, selon lequel ladite étape de filtrage numérique élimine d'autres restes de fréquences au-dessus et au-dessous de la gamme de fréquences, dans laquelle ledit rythme cardiaque se situe, et sert à supprimer le ronflement dans la ligne d'alimentation à environ 50-60 hertz.
- 17. Procédé selon la revendication 16, selon lequel ladite étape de calcul de ladite moyenne mobile comprend les étapes consistant à:

utiliser un ordinateur pour calculer une moyenne mobile desdits échantillons numériques élevés au carré conformément à l'expression mathématique:

$$Y_{N} = \frac{1}{\sum_{i=0}^{N-1} \sum_{i=0}^{N-1} X_{N-i}}$$

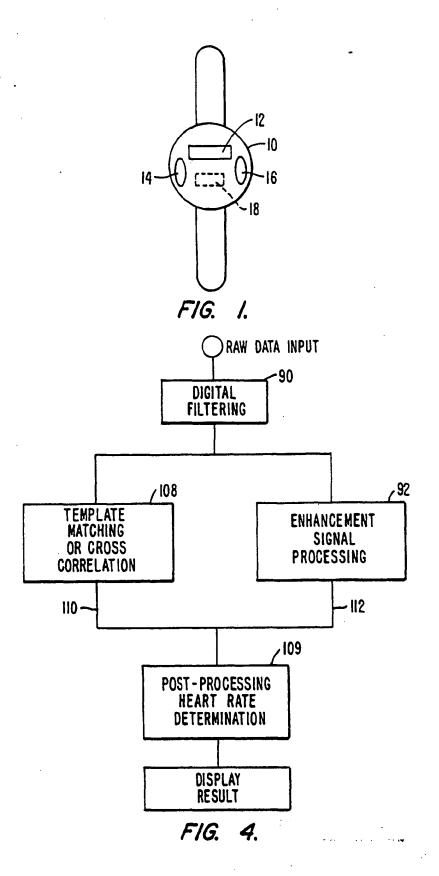
25 dans laquelle

 Y_N représente la moyenne mobile pour n'importe quel instant particulier d'échantillonnage N, X_{N-1} représente l'amplitude de l'échantillon de données numériques à l'instant N-i.

- 30 18. Procédé selon la revendication 14, selon lequel ladite élévation au carré de l'amplitude est exécutée par consultation de carrés dans une table de consultation.
 - 19. Procédé selon l'une quelconque des revendications 13 à 18, comprenant en outre une opération servant à distinguer des impulsions provoquées par les battements cardiaques par rapport à d'autres impulsions, moyennant les étapes consistant à:
 - (a) éliminer des impulsions qui arrivent à des instants incompatibles avec une variation plausible d'un battement au suivant dans le rythme cardiaque, et ce comme représentant des artéfacts plutôt que dès battements cardiaques; et
 - (b) éliminer des impulsions ayant des amplitudes variant de plus d'une valeur prédéterminée par rapport à des impulsions reçues précédemment et représentant des battements cardiaques.
 - 20. Procédé selon la revendication 19, mettant en oeuvre les étapes consistant à:
 - (c) identifier une impulsion d'artéfact arrivant avant un instant d'arrivée attendu d'une impulsion de battement cardiaque; et
 - (d) identifier une impulsion qui arrive audit instant d'arrivée attendu en tant qu'impulsion de battement cardiaque uniquement si ladite impulsion d'artéfact a disparu.
- 21. Procédé selon la revendication 19 ou 20, selon lequel l'étape (a) comprend l'élimination d'impulsions qui arrivent à un instant indicatif d'une variation de la période entre des battements cardiaques, supérieure à environ 6,75 %.
 - 22. Procédé selon la revendication 19, 20 ou 21, selon lequel l'étape (b) comprend l'élimination d'impulsions qui ont des amplitudes variant de plus de 50 % par rapport à des impulsions reçues précédemment et représentant des battements cardiaques.
 - 23. Procédé selon la revendication 2, selon l'étape (c) comprend les étapes à:

au bout d'environ 50 % d'une période entre une demière impulsion de battement cardiaque et ledit instant d'arrivée attendu d'une impulsion de battement cardiaque, régler un seuil d'impulsion de bruit pour détecter des impulsions d'artéfact;

réduire ledit seuil d'impulsion de bruit jusqu'audit instant d'arrivée attendu; et identifier des impulsions qui ne sont pas des battements cardiaques, au-dessus dudit seuil d'impulsion de bruit, en tant qu'impulsions d'artéfact.



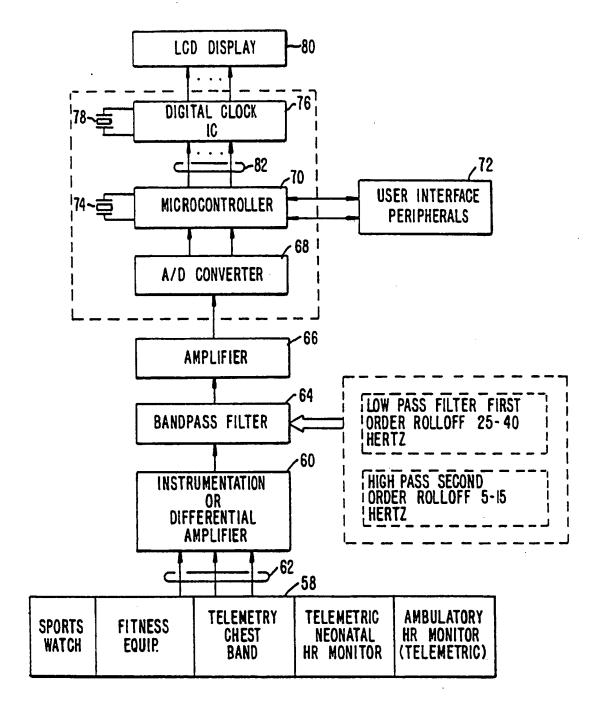
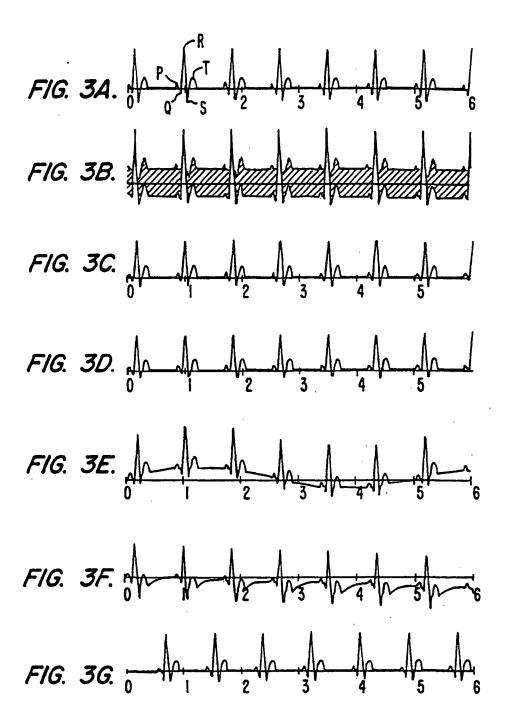
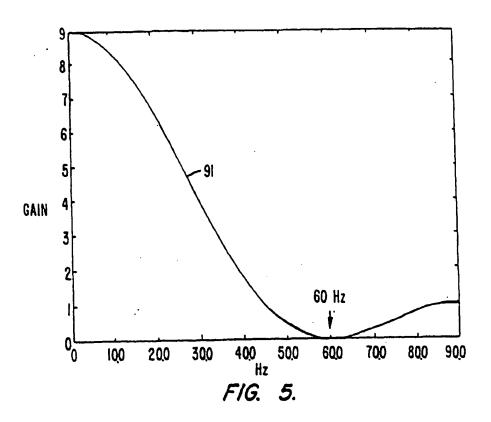
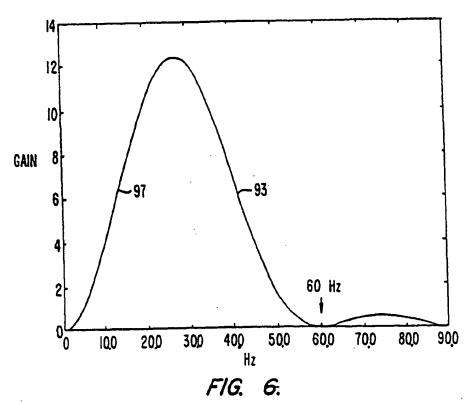


FIG. 2.







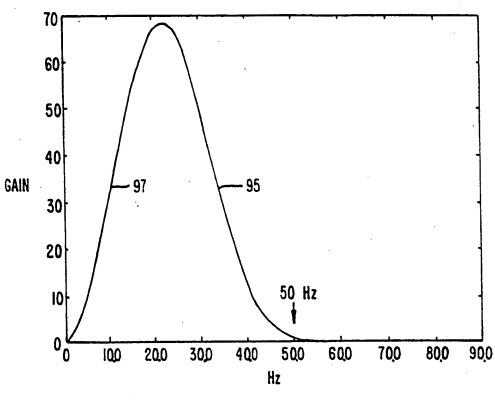
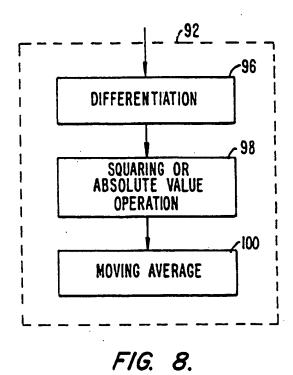


FIG. 7.



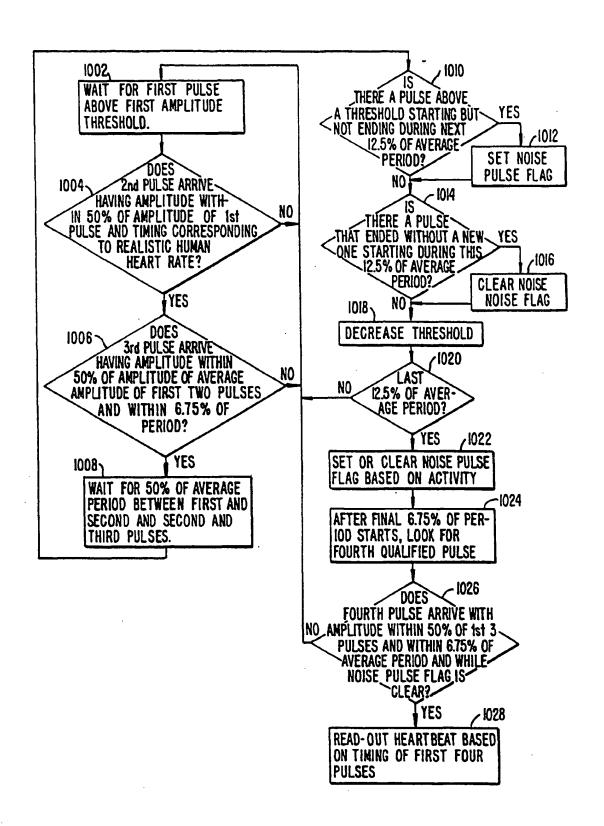


FIG. 10.

